polymyxin B, and 10 milligrams of hydrocortisone in a suitable and harmless vehicle. It may also contain one or more suitable and harmless buffers, dispersants, and solvents. Its neomycin sulfate content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of milligrams of neomycin that it is represented to contain. Its polymyxin B sulfate content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of polymyxin B that it is represented to contain. It is sterile. The pH is not less than 2.0 and not more than 4.5. The neomycin sulfate used conforms to the standards prescribed by §444.42(a)(1). The polymyxin B sulfate used conforms to the standards prescribed by §448.30(a)(1) of this chapter.

(2) *Labeling.* It shall be labeled in accordance with the requirements of §432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The neomycin sulfate used in making the batch for potency, loss on drying, pH, and identity.

(*b*) The polymyxin B sulfate used in making the batch for potency, loss on drying, pH, and identity.

(*c*) The batch for neomycin content, polymyxin B content, sterility, and pH.

(ii) Samples required:

(*a*) The neomycin sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The polymyxin B sulfate used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*c*) The batch:

(*1*) For all tests except sterility: A minimum of six immediate containers.

(*2*) For sterility testing: 20 immediate containers, collected at regular intervals throughout each filling operation.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Neomycin content.* Proceed as directed in §436.105 of this chapter, preparing the sample for assay as follows: Dilute an accurately measured representative portion of the sample with sufficient 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), to the reference concentration of 1.0 microgram of neomycin per milliliter (estimated).

(ii) *Polymyxin B content.* Proceed as directed in §436.105 of this chapter, except add to each concentration of polymyxin B standard response line a quantity of neomycin equal to the amount present when the sample is diluted to contain 10 units of polymyxin B per milliliter. Prepare the sample for assay as follows: Dilute an accurately measured representative portion of the sample with sufficient 10 percent potassium phosphate buffer, pH 6.0 (solution 6), to the reference concentration of 10 units of polymyxin B per milliliter (estimated).

(2) *Sterility.* Proceed as directed in §436.20 of this chapter, using the method described in paragraph (e)(1) of that section.

(3) *pH.* Proceed as directed in §436.202 of this chapter, using the undiluted sample.

[41 FR 14186, Apr. 2, 1976; 46 FR 55091, Nov. 6, 1981, as amended at 50 FR 19919, May 13, 1985]

Subpart F—Dermatologic Dosage Forms

§444.520 Gentamicin sulfate dermatologic dosage forms.

§444.520a Gentamicin sulfate ointment.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Gentamicin sulfate ointment is gentamicin sulfate with suitable preservatives in a white petrolatum base. Each gram contains gentamicin sulfate equivalent to 1.0 milligram of gentamicin. Its potency is satisfactory if it is not less than 90 percent and not more than 135 percent of the number of milligrams of gentamicin that it is represented to contain. Its moisture content is not more than 1.0 percent. The gentamicin sulfate used conforms to the standards prescribed therefor by §444.20(a)(1).

(2) *Packaging.* In addition to the requirements of §432.1 of this chapter, it may be dispensed from a pressurized container wherein it is maintained in a compartment separate from the gas used to supply the pressure.

(3) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(4) *Requests for certification; samples.* In addition to the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The gentamicin sulfate used in making the batch for potency, loss on drying, pH, specific rotation, content of gentamicins C_1, C_{1a}, and C_2, and identity.

(*b*) The batch for gentamicin potency and moisture.

(ii) Samples required:

(*a*) The gentamicin sulfate used in making the batch: 10 packages, each containing not less than 500 milligrams.

(*b*) The batch: A minimum of five immediate containers.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place an accurately weighed representative portion of the ointment into a separatory funnel containing 50 milliliters of peroxide-free ether. Shake the sample and ether until homogeneous, add 20–25 milliliters of 0.1 *M* potassium phosphate buffer, pH 8.0 (solution 3), and shake well. Allow the layers to separate. Remove the buffer layer and repeat the extraction with new portions of the buffer and repeat any additional times necessary to insure complete extraction of the antibiotic. Combine the extractives and adjust to an appropriate volume to give a stock solution of convenient concentration. Further dilute with solution 3 to the reference concentration of 0.1 microgram of gentamicin per milliliter (estimated).

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

[39 FR 19046, May 30, 1974, as amended at 50 FR 19919, May 13, 1985]

§ 444.520b Gentamicin sulfate cream.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Gentamicin sulfate cream is gentamicin sulfate with one or more suitable emollients, dispersants, and preservatives in a suitable and harmless cream base. Each gram contains gentamicin sulfate equivalent to 1.0 milligram of gentamicin. Its potency is satisfactory if it is not less than 90 percent and not more than 135 percent of the number of milligrams of gentamicin that it is represented to contain. The gentamicin sulfate used conforms to the standards prescribed therefor by § 444.20(a)(1).

(2) *Packaging.* In addition to the requirements of § 432.1 of this chapter, it may be dispensed from a pressurized container wherein it is maintained in a compartment separate from the gas used to supply the pressure.

(3) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(4) *Requests for certification; samples.* In addition to the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The gentamicin sulfate used in making the batch for potency, loss on drying, pH, specific rotation, gentamicins C_1, C_{1a}, and C_2, and identity.

(*b*) The batch for gentamicin potency.

(ii) Samples required:

(*a*) The gentamicin sulfate used in making the batch: 10 packages, each containing not less than 500 milligrams.

(*b*) The batch: A minimum of five immediate containers.

(b) *Tests and methods of assay; potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place an accurately weighed representative portion of the cream into a separatory funnel containing approximately 50 milliliters of peroxide-free ether. Shake the sample and ether until homogeneous. Add 20 to 25 milliliters of 0.1*M* potassium phosphate buffer, ph 8.0 (solution 3), and shake gently to avoid gel formation. Allow the layers to separate. Remove the buffer layer and repeat the extraction procedure with each of three more 20 to 25 milliliter quantities of solution 3. Combine the buffer extractives and adjust to an appropriate volume to obtain a stock solution of convenient concentration. Further dilute with solution 3 to the reference concentration